

**OHIO DEPARTMENT OF MEDICAID**  
**PRIOR AUTHORIZATION HEPATITIS C TREATMENT**

DATE

MEMBER NAME	PREScriBER NAME
MEMBER MEDICAID ID NUMBER	PREScriBER NPI NUMBER
MEMBER DATE OF BIRTH	PREScriBER ADDRESS
PREScriBER FAX NUMBER	PREScriBER PHONE NUMBER

Only Hepatitis C treatment PA requests for members who meet the following guidelines will be approved. This PA form will cover up to the length authorized by the American Association for the Study of Liver Disease (AASLD) guidelines.

Please refer to the **APPENDIX** which lists the various regimens and the clinical situations for which they will be considered medically necessary according to the Ohio Department of Medicaid ODM criteria.

The PA must be approved prior to the 1<sup>st</sup> dose and include appropriate supporting documentation.

**PREFERRED REGIMENS**

**INFECTIOUS DISEASE AGENTS: HEPATITIS C-DIRECT ACTING ANTIVIRAL**

CLINICAL PA REQUIRED "PREFERRED"+	PA REQUIRED "NON-PREFERRED"
SOFOBUVIR/VELPATASVIR (generic of EPCLUSA) (Labeler 72626)	LEDIPASVIR/SOFOBUVIR (generic of HARVONI)
MAVYRET (glecaprevir and pibrentasvir)	SOVALDI (sofosbuvir)
	VOSEVI (sofosbuvir, velpatasvir, voxilaprevir)
	ZEPATIER (elbasvir and grazoprevir tablet)

Selection of regimen to be based upon the APPENDIX below and in accordance with AASLD/IDSA guidelines for those 18 years old and over (<https://www.hcvguidelines.org/>.) FDA approved pediatric formulations of direct acting antivirals (DAA) will be approved for those under the age of 18 years when used in accordance with current AASLD guidelines.

The following documentation must be submitted with initial request for consideration of approval:

<input type="checkbox"/> Active HCV infection verified by viral load within 180 days HCV RNA: _____ million IU/mL	Date _____
<input type="checkbox"/> HCV Genotype verified by lab Genotype <input type="checkbox"/> 1a <input type="checkbox"/> 1b <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6	
Hepatitis fibrosis stage: _____ Date: _____	
Method(s) used: _____	
<input type="checkbox"/> Patients scheduled to receive an HCVNS3 protease inhibitor (i.e. grazoprevir, voxilaprevir, glecaprevir) should be assessed for a history of decompensated liver disease and liver disease severity using the Child-Turcotte-Pugh (CTP) score if cirrhosis is determined to be likely present (as evidenced by clinical findings, radiology, Metavir fibrosis score of F4, pathology findings or other laboratory markers (FibroTest/FibroSure/FIB-4 index).	
<input type="checkbox"/> Prescriber has discussed the importance of adherence to treatment plan, office visits, lab monitoring, imaging, procedures and to taking requested regimen as prescribed.	
<input type="checkbox"/> Patient does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions.	
<b>Ribavirin (RBV)-ineligible:</b> <ul style="list-style-type: none"><li>• CrCl&lt;50mL/min (unless dose is adjusted)</li><li>• Hypersensitivity to ribavirin</li><li>• History of severe or unstable cardiac disease</li><li>• Pregnant women and men with pregnant partners</li><li>• Diagnosis of hemoglobinopathy (e.g. thalassemia major, sickle cell anemia)</li><li>• Baseline platelet count &lt;70,000 cells/mm<sup>3</sup></li><li>• ANC&lt;1,500 cells/mm<sup>3</sup></li><li>• Hb&lt;12gm/dl in women or &lt;13g/dL in men</li></ul>	
<b>Low dose Ribavirin = 600mg/day and increased as tolerated</b>	
<b>For ANY regimen that includes ribavirin:</b> <ul style="list-style-type: none"><li>• For women of childbearing potential (and male patients with female partners of childbearing potential):<ul style="list-style-type: none"><li>○ Patient is not pregnant (or a male with a pregnant female partner) and not planning to become pregnant during treatment or within 6 months of stopping</li><li>○ Agreement that partners will use two forms of effective contraception during treatment and for at least 6 months after stopping</li><li>○ Verification that monthly pregnancy tests will be performed throughout treatment</li></ul></li></ul>	

**For treatment experienced patients, answer the following or include treatment notes that document this information:**

Prior treatment regimens, dates & outcomes, including reason for failure, if known (e.g. failed to complete prior therapy, failure of past therapy):

If reason for prior failure is non-adherence to prior therapy or failure to complete therapy, please document what is different this time to try to improve the outcome:

## APPENDIX

<b>Treatment naïve</b>
<b>No cirrhosis</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Mavyret 100/40 mg, three (3) tablets daily for 8 weeks (for GT5/6 and/or HIV/HCV co-infection, 12 weeks is recommended)</li> <li><input type="checkbox"/> sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks</li> </ul>
<b>Compensated cirrhosis, HIV negative</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Mavyret 100/40 mg, three (3) tablets daily for 8 weeks</li> <li><input type="checkbox"/> sofosbuvir/velpatasvir 400/100, one tablet daily for 12 weeks (for GT3, add weight based RBV if Y93H positive)</li> </ul>
<b>Compensated cirrhosis, HIV positive</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Mavyret 100/40 mg, three (3) tablets daily for 12 weeks</li> <li><input type="checkbox"/> sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks (for GT3, add weight based RBV if Y93H positive)</li> </ul>
<b>Treatment experienced</b>
<b>Sofosbuvir-based regimen</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Mavyret 100/40 mg, three (3) tablets daily for 16 weeks</li> </ul>
<b>NS3/4 protease inhibitor inclusive regimen (e.g. Zepatier)</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Vosevi 400/100/100 mg, one tablet daily for 12 weeks</li> </ul>
<b>Mavyret</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Vosevi 400/100/100 mg, one tablet daily for 12 weeks (if compensated cirrhosis, add weight-based RBV)</li> </ul>
<b>Vosevi or sofosbuvir + Mavyret</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Vosevi 400/100/100 mg, one tablet daily + weight-based RBV for 24 weeks</li> </ul>
<b>GT 3 only: sofosbuvir/NS5A (e.g. Harvoni)</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Vosevi 400/100/100 mg, one tablet daily + weight-based RBV for 12 weeks</li> </ul>
<b>Re-infection of Allograft Liver after Transplant</b>
<b>DAA-treatment naïve, no decompensated cirrhosis</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Mavyret 100/40 mg, three (3) tablets daily for 12 weeks</li> <li><input type="checkbox"/> sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks</li> </ul>
<b>DAA-treatment experienced, no decompensated cirrhosis</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Vosevi 400/100/100 mg, one tablet daily for 12 weeks</li> </ul>
<b>IF multiple negative baseline characteristics, consider</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Vosevi 400/100/100 mg, one tablet daily + low dose RBV for 12 weeks</li> </ul>
<b>Treatment naïve, decompensated cirrhosis</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> sofosbuvir/velpatasvir 400/100 mg, one tablet daily + low dose RBV for 12 weeks</li> </ul>
<b>Treatment experienced, decompensated cirrhosis (Child-Pugh B or C ONLY)</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> sofosbuvir/velpatasvir 400/100 mg, one tablet daily + low dose RBV for 24 weeks</li> </ul>
<b>Decompensated Cirrhosis</b>
<b>No prior sofosbuvir or NS5A failure</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> sofosbuvir/velpatasvir 400/100 mg + weight-based RBV daily for 12 weeks (low dose RBV recommended for Child-Pugh class C cirrhosis)</li> <li><input type="checkbox"/> sofosbuvir/velpatasvir 400/100 mg daily for 24 weeks (will be approved only for patients with documented ineligibility for RBV)</li> </ul>
<b>Prior sofosbuvir or NS5A failure</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> sofosbuvir/velpatasvir 400/100 mg + weight-based RBV daily for 24 weeks (low dose RBV if Child-Pugh C)</li> </ul>
<b>Other Treatment Regimen</b>
<b>Genotype, treatment history, and extent of liver disease:</b>

**Drug names, doses and durations:**

**Clinical rationale for selecting regimens other than those outlined above:**

☐ I attest that I am a member of the prescriber's office in accordance with rule 5160-9-03 of the Ohio Administrative Code. Only the prescribing provider or a member of the prescribing provider's staff may request prior authorization.

Prescriber's Signature or staff of prescriber: \_\_\_\_\_

Please print your name: \_\_\_\_\_

Date: \_\_\_\_\_

Fax To: Ohio Department of Medicaid

Fax: **(800) 396 – 4111** Helpdesk Phone Number: **(877) 518 – 1546**

Hours: Monday – Friday 8:00 am to 8:00 pm EST